UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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| UNITED STATES OF AMERICA<br><br>Plaintiff,<br><br>v.<br><br>TEVA PHARMACEUTICALS USA, INC., et al.,<br><br>Defendants. | ) | Civil Action No. 20-11548-NMG |

ORDER ON DEFENDANTS' MOTION TO
COMPEL INTERNAL HHS-OIG COMMUNICATIONS
[Docket No. 79]

January 25, 2023

Boal, M.J.

In this action, the United States alleges that defendants Teva Pharmaceuticals USA, Inc. and Teva Neuroscience, Inc. (collectively, "Teva") improperly paid millions of dollars to charitable foundations with the intent and understanding that the money would be used to subsidize patients' out-of-pocket expenses for a drug manufactured by Teva. Pursuant to Rule 37 of the Federal Rules of Civil Procedure, Teva has moved to compel the United States to produce certain internal Department of Health and Human Services Office of Inspector General ("HHS-OIG") communications. Docket No. 79.[1] For the following reasons, I deny the motion.

[1] On September 6, 2022, Judge Gorton referred the motion to the undersigned. Docket No. 82.

## I. RELEVANT BACKGROUND

### A. The Government's Allegations

The United States alleges that Teva violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("AKS") and caused the submission of false claims to Medicare under the False Claims Act, 31 U.S.C. §§ 3279 et seq. ("FCA") by knowingly and willfully paying the out-of pocket or copay expenses of Medicare patients who took its multiple sclerosis ("MS") drug, Copaxone. Complaint at ¶ 1. According to the United States, Teva covered the patients' copays through and in conspiracy with Advanced Care Scripts, Inc. ("ACS"), a specialty pharmacy that also served as Teva's vendor, and The Assistance Fund, Inc. ("TAF") and Chronic Disease Fund ("CDF"), two patient assistance foundations. See id. at ¶¶ 2-6.

CDF and TAF are charitable foundations. See id. at ¶ 1. During the period of time relevant to this action, each operated a fund for MS patients to cover the copays for a number of available MS medications. Id. at ¶ 3. The government alleges that Teva worked with ACS to ensure that its donations to CDF and TAF were used solely for Copaxone copay assistance. See generally id. at ¶¶ 3-6, 56, 64, 76-78. Between December 2006 and December 2015, Teva donated to CDF and TAF more than $328 million in 66 payments. See Ex. 1 to Complaint. The complaint alleges that those contributions were intended to increase sales of and generate Medicare claims for Copaxone. See id. at ¶¶ 2-3; 54-65.

The United States alleges that Teva acted knowingly and willfully in part because it knew that federal law prohibited it from covering a Medicare patient's copay either directly or indirectly by using a foundation as a pass-through vehicle. Id. at ¶¶ 66-68. Teva was aware of two public guidance documents—HHS-OIG's 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees ("2005 SAB"), 70 Fed. Reg. 70623 (Nov.

22, 2005) and HHS-OIG's 2014 Supplemental Special Advisory Bulletin, Independent Charity Patient Assistance Programs ("2014 SAB"), 79 Fed. Reg. 31120 (May 30, 2014) (collectively, the "SABs"), that were published in the federal register. Id. at ¶ 67. Those documents warn that in order to avoid violating the AKS, copay assistance foundations "must not function as a conduit for payments by the pharmaceutical manufacturer to patients," and that a pharmaceutical manufacturer should not "solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products." Id.

CDF and TAF each also received Advisory Opinions from HHS-OIG. Id. at ¶¶ 69-70. Those Advisory Opinions noted that the foundations' conduct would be low risk under the AKS so long as they did "not provide Donors with any data that would facilitate the Donor in correlating the amount or frequency of its donations with the amount or frequency of the use of its products or services," and "Donors would not be permitted to earmark contributions for specific Specialty Medications." Id. The Advisory Opinions stated that they were based "solely on the facts and information presented" to HHS-OIG and that they "may not be relied on by any persons other than" the requestor of the opinion. Docket No. 1-26 at 14, 15.

Teva maintains that it relied in good faith upon an objectively reasonable interpretation of the SABs, and that the SABs were vague and ambiguous and did not warn Teva away from its interpretation. Docket No. 79-1 at 9.

B. Teva's Discovery Requests Concerning HHS-OIG Internal Communications

On November 9, 2021, Teva served its First Set of Requests for Production of Documents on the United States. Docket No. 79-1 at 9. Request Nos. 22, 23, 26, 28, and 29 sought production of materials related to OIG's drafting, interpretation, application, and enforcement of

the SABs as well as the CDF and TAF Advisory Opinions. Id. Specifically, Teva requested that the government produce the following documents:

> 22. All documents in HHS OIG's possession concerning or relating to CDF's or TAF's co-pay assistance for MS patients and/or Teva's donations to patient assistance charities between January 1, 2006 to December 31, 2017.
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> 23. All documents in HHS OIG's possession concerning CDF or TAF between January 1, 2006 and December 31, 2017.
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> 26. All documents, regardless of their creation date, concerning, referenced, identified, relied on, consulted in preparing, or otherwise used in drafting the 2005 HHS-OIG Guidance, the 2014 HHS-OIG Guidance, HHS-OIG Advisory Opinion 10-07, or HHS-OIG Advisory Opinion 06-10 and any modifications thereof.
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> 28. All documents, regardless of their creation date, including but not limited to memoranda, reports, and internal communications, concerning the interpretation and/or application of the 2005 HHS-OIG Guidance, the 2014 HHS-OIG Guidance, HHS-OIG Advisory Opinion 10-07, or HHS-OIG Advisory Opinion 06-10 and any modifications thereof.
>
> 29. All documents, regardless of their creation date, including but not limited to memoranda, reports, and internal communications, concerning the enforcement of the 2005 HHS-OIG Guidance, the 2014 HHS-OIG Guidance, HHS-OIG Advisory Opinion 10-07, or HHS-OIG Advisory Opinion 06-10 and any modifications thereof.

Docket No. 79-2. The government objected to these requests on the grounds that they were overly broad, unduly burdensome, vague, and beyond the scope of permissible discovery under Rule 26 because they seek irrelevant information from internal agency deliberations that is protected by the attorney-client or deliberative process privileges. Id.; see also Docket No. 99 at 5. In an attempt to resolve the dispute without court intervention, the parties exchanged correspondence on these items for several months. Docket No. 99 at 5.

On May 11, 2022, the government produced to Teva communications between HHS-OIG and CDF and TAF as part of their Advisory Opinion requests. Id. It also produced documents

that had previously been produced in response to Freedom of Information Act ("FOIA") requests concerning the 2005 and 2014 SABs. Id.; see also Docket No. 79-1 at 10.

Following additional discussions between the parties, the government agreed to a compromise previously offered by Teva on April 4, 2022 to produce all internal HHS-OIG documents (including communications) relating to or concerning the 2005 or 2014 SABs that were prepared or created within the twelve months preceding issuance of the applicable document. Docket No. 79-1 at 10; Docket No. 99 at 5. The government subsequently served Teva with a privilege log on July 21, 2022. Docket No. 79-1 at 10. The privilege log listed 212 documents consisting of previously produced redacted documents and additional documents that had been withheld entirely. Id. After further discussions between the parties, this motion followed.

By its motion, Teva sought an order compelling the government's full responses to Request Nos. 22, 23, 26, 28, and 29 "as originally drafted." Docket No. 108 at 4. At the November 16, 2022 hearing on this matter, however, Teva's counsel stated that it was seeking only documents that relate to the 2014 SAB and "in particular the interpretations and what led to the 2014 guidance." See Docket No. 130 at 19. In supplemental briefing submitted after the hearing, Teva further limited its requested relief to:

> An *in camera* review of all internal OIG documents (including communications) relating to or concerning the 2005 or 2014 OIG Bulletins that were prepared or created within the 12 months preceding issuance of the 2014 OIG Bulletin (May 30, 2014) and included within the Government's Sept. 27, 2022 privilege log.

Docket No. 126 at 3.

## II. ANALYSIS

### A. Standard Of Review

"Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case." Fed. R. Civ. P. 26(b)(1). Whether discovery is proportional to the needs of the case depends on, among other things, "the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of discovery in resolving the issues, and whether the expense of the proposed discovery outweighs its likely benefit." Id.

If a party fails to respond to requests for production of documents or interrogatories, the party seeking discovery may move to compel production of the requested information. See Fed. R. Civ. P. 37(a)(3). "[T]he party seeking an order compelling discovery responses over the opponent's objection bears the initial burden of showing that the discovery requested is relevant." Torres v. Johnson & Johnson, No. 3:18-10566-MGM, 2018 WL 4054904, at *2 (D. Mass. Aug. 24, 2018) (citation omitted). "Once a showing of relevance has been made, the objecting party bears the burden of showing that a discovery request is improper." Id. (citation omitted).

### B. Teva Has Failed To Show That Internal HHS-OIG Communications Are Relevant

Teva argues that internal HHS-OIG communications regarding the SABs are relevant to its "good faith interpretation" defense. See Docket No. 79-1 at 12-13. Teva correctly argues that "non-public agency statements might be used to support a good faith defense in cases where there is some evidence that the defendant acted in the good faith belief that his conduct was lawful, and that the agency's internal analysis bolsters the reasonableness of the defendant's interpretation of the law." United States v. Facteau, No. 15-CR-10076-ADB, 2015 WL

6509120, at *4 (D. Mass. Oct. 28, 2015) (citing United States v. Lachman ("Lachman II"), 521 F.3d 12, 19 (1st Cir. 2008)). The defendant, however, must provide a "foundation for a good-faith defense based on [that alleged interpretation]." Lachman II, 521 F.3d at 19; see also Facteau, 2015 WL 6509120 at *4 (denying discovery of internal agency documents because even though defendants had stated their intention to raise a good faith defense, they had "not adequately articulated specifically how the FDA's internal discussions" were relevant to their interpretation of the statute at issue).

Teva has failed to provide an adequate foundation for its good faith defense in this case. In response to the United States' interrogatories asking it to state the basis for its good faith defense, Teva did not identify the nature of its interpretation of the SABs or provide any evidence that it held any contemporaneous interpretation of the SABs. Rather, it cited to the SABs themselves and its contracts with CDF, TAF, ACS, and AssistRx, without identifying any portions thereof upon which it relied. See Docket No. 92-5. While Teva relies on the testimony of Patricia Glover, a former compliance officer, that she thought the 2014 bulletin "focused" on manufacturers more than the 2005 bulletin, Docket No. 126 at 2, it has not identified any ambiguities or any interpretation of the guidance documents, the AKS or the FCA that Teva allegedly relied upon in good faith.[2] Moreover, Teva has provided no basis to conclude that the internal communications of individual HHS-OIG employees played any role in Teva's purported understanding or interpretation of the OIG guidance. Accordingly, Teva has failed to show the relevance of the requested documents.

[2] Contrary to Teva's suggestion, the requirement for a foundation for its good faith defense does not require it to proffer evidence to support its discovery request. See Docket No. 108 at 1-2. Rather, this Court finds that Teva must articulate with specificity the basis of its defense and that it has failed to do so.

C. Teva Has Failed To Show A Basis For Conducting An *In Camera* Review Of The Documents And Information Withheld On Privilege Grounds

The government has asserted that many of the internal communications that Teva seeks are protected by the attorney-client privilege and/or deliberative process privilege. It has provided a privilege log as well as the Declaration of Susan A. Edwards, Chief of the Industry Guidance Branch, Office of the Counsel to the Inspector General Office ("OCIG"), in the Office of Inspector General for the Department of Health and Human Services (Docket No. 99-1) ("Edwards Decl.") in support of its assertion of privilege. With respect to the attorney-client privilege, Teva does not challenge the adequacy of the privilege log or Ms. Edward's declaration. Rather, it simply argues that "[i]t is hard to believe that ***every single*** internal HHS-OIG document responsive to the parties' agreed terms involved the provision of legal advice and is protected from disclosure in full." Docket No. 79-1 at 20 (emphasis in original). However, it is not surprising that a large of percentage of the documents responsive to the requests were privileged because Teva's requests center on OCIG—a legal department within HHS-OIG whose very function is to provide legal advice to the Inspector General. See Edwards Decl. at ¶¶ 4, 9. Indeed, Ms. Edwards supervises the Industry Guidance Branch ("IGB"), a branch within OIG which consists of attorneys and legal support staff. Id. at ¶ 4. Per Ms. Edwards, the requested documents were primarily drafted by IGB. See id. at ¶ 9.

With respect to the deliberative process privilege, Teva raises no argument as to the applicability of the privilege to the subject documents. Rather, it argues that its purported need for the internal HHS-OIG communications should override the privilege. Docket No. 79-1 at 17. The deliberative process privilege is "a qualified one" and "not absolute." Id. at 885 (internal citations omitted). In deciding whether the deliberative process privilege should be overcome, a court "should consider, among other things, the interests of the litigants, society's interest in the

accuracy and integrity of factfinding, and the public's interest in honest, effective government." In re Pharmaceutical Industry Average Wholesale Price Litig., 254 F.R.D. 35, 40 (D. Mass. 2008) (quoting Texaco P.R., Inc. v. Dep't of Consumer Affairs, 60 F.3d 867, 885 (1st Cir. 1995)). "The Court must balance the public interest in the protection of the deliberative process against the movant's particularized need for the information as evidence in the case before it." Id. (citations omitted).

Courts consider numerous factors when balancing the competing interests involved, including:

> (i) the relevance of the evidence sought to be protected; (ii) the availability of other evidence; (iii) the 'seriousness' of the litigation and the issues involved; (iv) the role of the government in the litigation; and (v) the possibility of future timidity by government employees who will be forced to recognize that their secrets are violable.

Id. (quoting In re Franklin Nat'l Bank Sec. Litig., 478 F.Supp. 577, 583 (E.D.N.Y. 1979)).

As the government acknowledges, there are factors that favor disclosure, including that the United States is the plaintiff in this case and the case involves serious allegations. However, the remaining factors weigh in favor of nondisclosure. First, as discussed above, Teva has not shown that the internal HHS-OIG communications are relevant in this case. Teva argues that internal HHS-OIG communications interpreting, applying, and discussing the SABs and Advisory Opinions are relevant because "they may shed invaluable light on OIG's own opinions" regarding the SABs and Advisory Opinions. Docket No. 79-1 at 17-18. However, the internal communications of individual HHS-OIG employees do not represent the position or interpretation of the agency. Edwards Decl. at ¶¶ 8, 13 ("[U]npublished drafts, preliminary analyses, or unfinished documents reflecting the opinions or suggestions of the authors and the comments from other OIG attorneys and personnel do not constitute the final position of OIG on

any other matter or recommendation unless and until they are embodied in a final published product (*i.e.*, the Special Advisory Bulletins and advisory opinions)." The Advisory Opinions and SABs are publicly available, and Teva has not provided any reason to believe that internal HHS-OIG communications would shed light on its own interpretation of those documents.

Second, other evidence regarding Teva's alleged defenses is available. The best evidence of Teva's scienter is its own documents and witnesses. In addition, it may seek, for example, discovery regarding other drug manufacturers' interpretation of the SABs. Finally, the release of internal agency deliberations would likely "discourage candid discussion within the agency and thereby undermine [HHS-OIG's] ability to perform effectively its assigned function." Am. Fed. Of Gov't Emps., AFL-CIO v. U.S. Dep't of Health & Human Servs., 63 F.Supp.2d 104, 108 (D. Mass. 1999). Here, HHS-OIG attorneys reasonably expect that the substance of their internal discussions will be kept confidential, and disclosure would likely chill the internal sharing of views of personnel involved in future SABs and guidance documents. See Edwards Decl. at ¶¶ 11, 14-16. Accordingly, I find that Teva has not shown that the deliberative process should be overcome in this case or that this Court should perform an in camera review of the subject documents.

## III. ORDER

For the foregoing reasons, I deny Teva's motion to compel.

/s/ Jennifer C. Boal
JENNIFER C. BOAL
U.S. MAGISTRATE JUDGE